TESTIMONY OF

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CENTERS FOR MEDICARE & MEDICAID SERVICES

BEFORE THE

HOUSE SMALL BUSINESS COMMITTEE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

ON

DURABLE MEDICAL EQUIPMENT, PROTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) COMPETITIVE BIDDING PROGRAM

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CMS
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Good morning Chairwoman Velazquez and distinguished members of the Committee. I am pleased to be here today on behalf of the Centers for Medicare & Medicaid Services (CMS) to discuss the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program mandated by the Medicare Modernization Act (MMA) of 2003. This major initiative will reduce beneficiary out-of-pocket costs, improve the accuracy of Medicare's DMEPOS payments, help combat supplier fraud, and ensure beneficiary access to high quality DMEPOS items and services.

Overview

CMS is the largest purchaser of health care in the United States, serving over 92 million Medicare, Medicaid, and SCHIP beneficiaries. Medicare alone covers roughly 44 million individuals, with total Medicare benefit outlays projected to reach $454 billion in Fiscal Year (FY) 2008.[1] Each year, DMEPOS suppliers provide items and services including power wheelchairs, oxygen equipment, walkers and hospital beds to over 10 million people with Medicare. Reasonable Medicare payment amounts for DMEPOS are especially important considering the dramatic growth in expenditures for these items.

Medicare traditionally pays for DMEPOS items and services using fee schedule rates for covered items. In general, fee schedule rates are calculated using historical supplier charge data that may not be reflective of an appropriate payment amount for today's market. As the following chart illustrates, relying on historical charge data has resulted in Medicare rates that are often higher

[1] Department of Health and Human Services, Budget in Brief: FY 2008 at 51.

than prices charged for identical items and services when furnished to non-Medicare customers. Medicare beneficiaries and taxpayers bear the cost of these inflated charges.

Comparison Prices

DMEPOS Device (rank by use)	*CMS Fee (% above average online price)*	*Illustrative Internet Pricing*	*CMS payment above average online price*
Oxygen concentrator (#1)	$2,380 (+352%)	$677	$1,703
Standard power mobility device (#3)	$4,023 (+185%)	$2,174	$1,849
Hospital bed (#4)	$1,825 (+242%)	$754	$1,071
Continuous positive airway pressure device (#5)	$1,452 (+517%)	$281	$1,171
Respiratory assist device BIPAP (#18)	$3,335 (+247%)	$1,348	$1,987

Much of the growth in Medicare expenditures can be attributed to a few high cost, high volume product categories that have been included in round one of competitive bidding. The three attached charts show growth in expenditures for these items. The first chart shows growth in Medicare expenditures for wheelchairs from 1995 to 2006. This chart indicates that growth in expenditures for manual wheelchairs has been fairly modest, with total allowed charges increasing by 64 percent from $184 million in 1995 to $301 million in 2006. Medicare currently pays approximately $560 over 13 months for a standard manual wheelchair. By comparison, the growth in expenditures for power mobility devices or PMDs has been significant, with total allowed charges increasing by 1,561 percent from $59 million in 1995 to $980 million in 2006. Medicare pays approximately $4,000 in a lump sum payment for a standard power wheelchair. Just to clarify, the Medicare allowed charge data in this chart reflect expenditures for the base wheelchairs and does not include expenditures for many high cost accessories that go along with these wheelchairs, such as certain power seating systems used with power wheelchairs that are priced at approximately $9,000 a piece based on manufacturer suggested retail prices (MSRPs). In many cases, MSRP data is used to set Medicare fee schedule amounts for new technology items when the historical supplier charge data that would otherwise be used to set the fee schedule amounts are not available. The competitive bidding program offers the advantage of

allowing Medicare payment amounts to be established for these items based on supplier bids for furnishing items rather than prices set by manufacturers for their equipment.

The second chart shows the dramatic growth in expenditures for negative pressure wound therapy (NPWT) suction pumps and accessories. Medicare currently pays approximately $1,700 per month for the rental of the pump alone and expenditures for this category have grown from $30 million in 2001 to $248 million in 2006. This is another example of a fee schedule amount for a newer technology item that was established based on MSRP.

The third and final chart contains expenditure data for oxygen and oxygen equipment, the top DMEPOS category in terms of Medicare expenditures. Medicare expenditures in this category have increased from $2.2 billion in 2002 to almost $2.8 billion in 2006.

In an attempt to find an effective method for setting reasonable Medicare payments for DMEPOS and related services, the Balanced Budget Act of 1997 (BBA 1997) authorized the Secretary of Health and Human Services to conduct up to five demonstration projects to test competitive bidding. The competitive bidding demonstration for DMEPOS was implemented by CMS at two sites: Polk County, Florida and the San Antonio, Texas area.

The DMEPOS bidding demonstrations showed that competitive bidding is a viable method of establishing appropriate Medicare payments. For example:

- Costs were reduced for the Medicare Program and for beneficiaries;
- Quality of items and services was maintained; and,
- Beneficiaries kept access to needed items and services.

In the demonstration programs, the Medicare Program implemented several safeguards that assured that beneficiaries continued to have access to high quality supplies and services. One of the most important safeguards was selecting multiple winning suppliers in each category so that the beneficiaries had a choice if they were not satisfied with their supplier. An independent analysis of the project performed by RTI International found high satisfaction levels with the suppliers in the demonstration. Cost savings in the demonstration averaged 20% in the three bids

at the two locations. The demonstration design assured that small businesses could compete on a level playing field with large suppliers. Since we chose multiple winners for each product category, we were able to choose both large and small suppliers to service beneficiaries in the demonstration areas. About three-quarters of the winning bidders in the demonstration were small suppliers, defined by the Small Business Administration at the time as under $5 million in sales per year.[2]

It must also be noted that much of the observed fraud in the DMEPOS sector can be linked to high Medicare payment amounts for DMEPOS items. Since December 11, 2000, suppliers have been required to meet Medicare enrollment standards. Despite these enrollment standards, the Department of Health and Human Services, Office of Inspector General (OIG), has conducted several investigations of suppliers of DMEPOS and other items to determine the legitimacy of their businesses and has uncovered many examples of fraud and abuse. Examples of the types of fraud and abuse that were discovered include:

- Billing for items and services not performed;
- Billing for a more expensive item or service than was rendered;
- Billing separately for several items or services that should be combined into one billing;
- Billing twice for the same item or service;
- Billing for more expensive equipment or supplies than were used;
- Offering or receiving kickbacks (that is, offering or accepting something in return for services);
- Offering or accepting a bribe to use a particular service or company;
- Providing unnecessary services; and
- Submitting false cost reports.

Despite the combined resources and attention of CMS, the OIG and the Department of Justice (DOJ), the fraudulent business practices of some DMEPOS suppliers continue to cost the Medicare program millions of dollars. DMEPOS competitive bidding is expected to help

[2] Hoerger, Thomas, et al., Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report, RTI International, 2003.

address these issues, in part, by making pricing for DMEPOS and services more competitive. In addition, under the DMEPOS competitive bidding program, Medicare will only contract with suppliers that meet eligibility, financial, and quality standards and are accredited by independent accrediting organizations. This will also help deter fraud.

While the BBA-authorized demonstrations focused on the potential for more competitive pricing for DMEPOS, CMS also sustained and improved initiatives during this timeframe to address fraud and abuse activities. CMS concluded that much of the observed fraud in the DMEPOS sector can be directly tied to provider enrollment issues, and have focused its efforts to address these problems. CMS has observed that these fraudulent activities tend to concentrate in high vulnerability areas of the country such as Los Angeles, Miami and Houston where there are a large number of beneficiaries and DMEPOS providers/suppliers.

Over the last 18 months, CMS and OIG, with important input from DOJ, have identified and documented a significant amount of fraud being committed by DMEPOS suppliers in Miami and the Los Angeles metropolitan area. Both regions of the country have high numbers of Medicare beneficiaries and DMEPOS suppliers, giving rise to a heightened risk for fraud. Working with the OIG and DOJ, CMS is encouraged by the agencies' targeted initiatives in these geographic areas to protect Medicare beneficiaries from fraudulent suppliers.

MMA Reforms

The MMA mandated competitive bidding for certain DMEPOS items and services after the BBA-authorized demonstration project in Texas and Florida produced significant savings for beneficiaries and taxpayers without hindering access or quality. The MMA contained three key provisions: (1) the application of quality standards by independent accreditation organizations to ensure high quality and good customer service, (2) financial standards to ensure that contract suppliers are viable entities capable of providing consistent and high quality service to beneficiaries, and (3) competitive bidding to provide greater value to Medicare through more accurate pricing and to beneficiaries through reduced coinsurance payments. In addition, the law created the Program Advisory and Oversight Committee (PAOC). The PAOC – which has over 20 members drawn from the supplier and consumer community – has the specific role of

advising CMS during the development and implementation of DMEPOS competitive bidding. To date, the agency has held six meetings with the PAOC. More than 500 members of the public have attended these meetings.

Under the DMEPOS competitive bidding program, suppliers in a competitive bidding area will submit bids for selected DMEPOS items, and CMS will use those bids to establish Medicare payment amounts for the selected items. The purpose of the Medicare DMEPOS competitive bidding program is to harness marketplace dynamics to create incentives for suppliers to provide quality items and services in an efficient manner at a reasonable cost to Medicare beneficiaries while potentially producing significant savings for the Medicare program. Within five years of implementing the competitive bidding program, taxpayer savings are projected to exceed over $1 billion annually.

The MMA mandates that the programs be phased in so that competition occurs in 10 of the largest MSAs in 2007; 80 of the largest MSAs in 2009; and additional areas after 2009. To identify the areas with the most potential for savings, CMS selects the MSAs for purposes of competitive bidding in calendar years 2007 and 2009 by considering the following variables:

- The total population of the MSA.
- The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.
- The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.
- An MSA's geographic location.

The program provides important safeguards to ensure beneficiary access and quality, in addition to savings, as outlined below.

Quality and Accreditation Standards. The MMA required the establishment of quality standards for DMEPOS suppliers. These standards will be particularly important in ensuring that supplier quality is maintained during competitive bidding. The quality standards address suppliers' accountability, business integrity, provision of quality products to beneficiaries, and performance

management. CMS conducted a wide variety of activities to involve stakeholders (including many targeted specifically for small business suppliers) and the public in development of these standards.

- We conducted focus groups early in the development process to provide small suppliers with an opportunity to share concerns about the impact quality standards would have on their businesses.
- We consulted with various stakeholders, including small supplier business owners, physicians, homecare association members, trade association members, accreditation organizations, clinical experts, and industry attorneys.
- We presented draft quality standards to the PAOC to provide advice on the Medicare DMEPOS competitive bidding program and quality standards.
- On September 26, 2005 we posted the draft standards on our web site for a 60-day public comment period that ended November 28, 2005.
- We held a special Open Door Forum to explain the draft quality standards and solicit comments.

CMS received more than 5,600 comments on the draft quality standards. Based on these public comments, we have made significant revisions to reduce burden on small suppliers and ensure quality services for Medicare beneficiaries. The new quality standards reflect basic good business practices and certain product specific services. We expect that many suppliers already comply with the quality standards and have incorporated these practices into their daily operations.

Independent accrediting organizations will accredit suppliers that meet the quality standards. CMS has designated 10 entities as qualified to accredit DMEPOS suppliers, based on quality standards that were posted on the CMS web site in August 2006. For the first round of bidding, suppliers must have either been accredited or be pending accreditation before submitting a bid; therefore, the costs of accreditation and maintaining high quality services will be factored into suppliers' bids. All suppliers must be accredited before they are awarded a contract under the competitive bidding program

Financially viable business partners. The MMA specifies that we may not award a contract to a supplier unless that supplier meets financial standards. Evaluation of financial standards assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, financial standards for suppliers will also help maintain beneficiary access to quality services by ensuring that contract suppliers are viable entities able to consistently provide quality items and services to patients for the life of the contract. As part of the bid solicitation, each bidder submitted certain required financial documentation. CMS will evaluate each bidder's financial documentation to determine whether the supplier will be able to participate in the program and maintain viability for the duration of the contract period.

Beneficiary protections. We anticipate that competitive bidding will save money for beneficiaries and taxpayers, while ensuring beneficiary access to high-quality items. The following are examples of the beneficiary protections established in the competitive bidding program:

- Competitive bidding should reduce the amount Medicare pays for DMEPOS and bring the payment amounts more in line with that of a competitive market. Also, contract suppliers must submit claims for competitive bidding items on an assignment basis. These factors will help limit the burden on beneficiaries by reducing their out-of-pocket expenses. Out-of-pocket savings for beneficiaries who use DMEPOS will come from lower coinsurance, since beneficiaries pay 20 percent of the Medicare allowed payment amount for equipment, supplies and services.

- Contract suppliers will meet the newly established DMEPOS quality standards and accreditation requirements and will follow a business model that is beneficial to beneficiaries (such as meeting financial standards). The independent accrediting organizations play a key role in ongoing monitoring of supplier quality.

- A sufficient number of contract suppliers will be selected to meet beneficiary demand.

- For the first time in the history of the Medicare program, the performance of suppliers will be monitored through beneficiary satisfaction surveys that measure their level of satisfaction with the services they receive under the competitive bidding program.

- Beneficiaries may be protected from financial liability when a non-contract supplier furnishes them with a competitively bid item.

- When a physician specifically prescribes a particular brand name product or mode of delivery to avoid an adverse medical outcome, contract suppliers are required either to furnish that item or mode of delivery, to assist the beneficiary in finding another contract supplier in the competitive bidding area that can provide that item or service, or to consult with the physician to find a suitable alternative product or mode of delivery for the beneficiary.

- Beneficiaries will be able to obtain repairs of equipment they own from either a contract or non-contract supplier.

- Replacement parts needed to repair beneficiary-owned equipment may also be obtained by a beneficiary from either a contract or non-contract supplier, even if the parts are competitively bid items.

- Contract suppliers are required to make available the same range of products to beneficiaries that they make available to non-Medicare customers. For transparency, we will post on our web site a list of brands furnished by each contract supplier.

- Under the grandfathering rules, a beneficiary will have the opportunity to make arrangements with a non-contract supplier that will allow the beneficiary to continue to receive a rented item from the same supplier (grandfathered supplier) that had been furnishing the item to the beneficiary before the implementation of a competitive bidding program, provided the supplier is willing. If a supplier agrees to furnish "grandfathered" items to one beneficiary, it must furnish those items to all.

Small Supplier Considerations

In developing this important new program, CMS worked closely with suppliers, manufacturers and beneficiaries through a transparent public process. This process included many public meetings and forums, the assistance of the PAOC, which included representation from the small supplier community, small business and beneficiary focus groups, notice and comment rulemaking, and other opportunities to hear the concerns and suggestions of stakeholders. As a result, CMS' policies and implementation plan pay close attention to the needs of beneficiaries and suppliers, in particular small suppliers.

The first round of the DMEPOS competitive bidding program is currently underway. Bids have been submitted by interested suppliers and CMS is now starting the bid review process. During the implementation of this program, CMS adopted numerous strategies to protect beneficiary access to quality items and to ensure small suppliers have the opportunity to be considered for participation in the program. For example, CMS worked in close collaboration with the Small

Business Administration to develop a new, more appropriate definition of "small supplier" for this program. Under this definition, a small supplier is a supplier that generates gross revenues of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue rather than the previous standard of $5 million. We believe that $3.5 million is representative of small suppliers that provide DMEPOS to Medicare beneficiaries. Further, recognizing that it may be difficult for small suppliers to furnish all the product categories under the program, suppliers are not required to submit bids for all product categories. The final regulation implementing the program allows small suppliers to band together in "networks" in order to meet the requirement to serve the entire competitive bidding area. In addition, to help ensure that CMS has multiple suppliers, each bidder's estimated capacity, for purposes of bid evaluation only, will be limited to 20 percent of the expected beneficiary demand for a product category in a competitive bidding area (CBA). This policy will ensure multiple contract suppliers for each product category and we expect that it will result in more contract suppliers than are needed to meet demand for items and services. Most importantly, the regulation established a 30 percent target for small supplier participation in the program.

The financial standards and associated information collection that suppliers must adhere to as part of the bidding process were crafted in a way that considers small suppliers' business practices and constraints. We have limited the number of financial documents that a supplier must submit so that the submission of this information will be less burdensome for all suppliers, including small suppliers. We believe we have balanced the needs of small suppliers and the needs of beneficiaries in requesting documents that will provide us with sufficient information to determine the financial soundness of a supplier.

CMS recognizes that under existing Medicare law and policies, physicians and other treating professionals sometimes supply certain items of DMEPOS to their patients as part of their professional service. The competitive bidding program preserves this physician-patient relationship by allowing physicians and other treating practitioners to continue supplying certain items to their patients without participating in the bidding process.

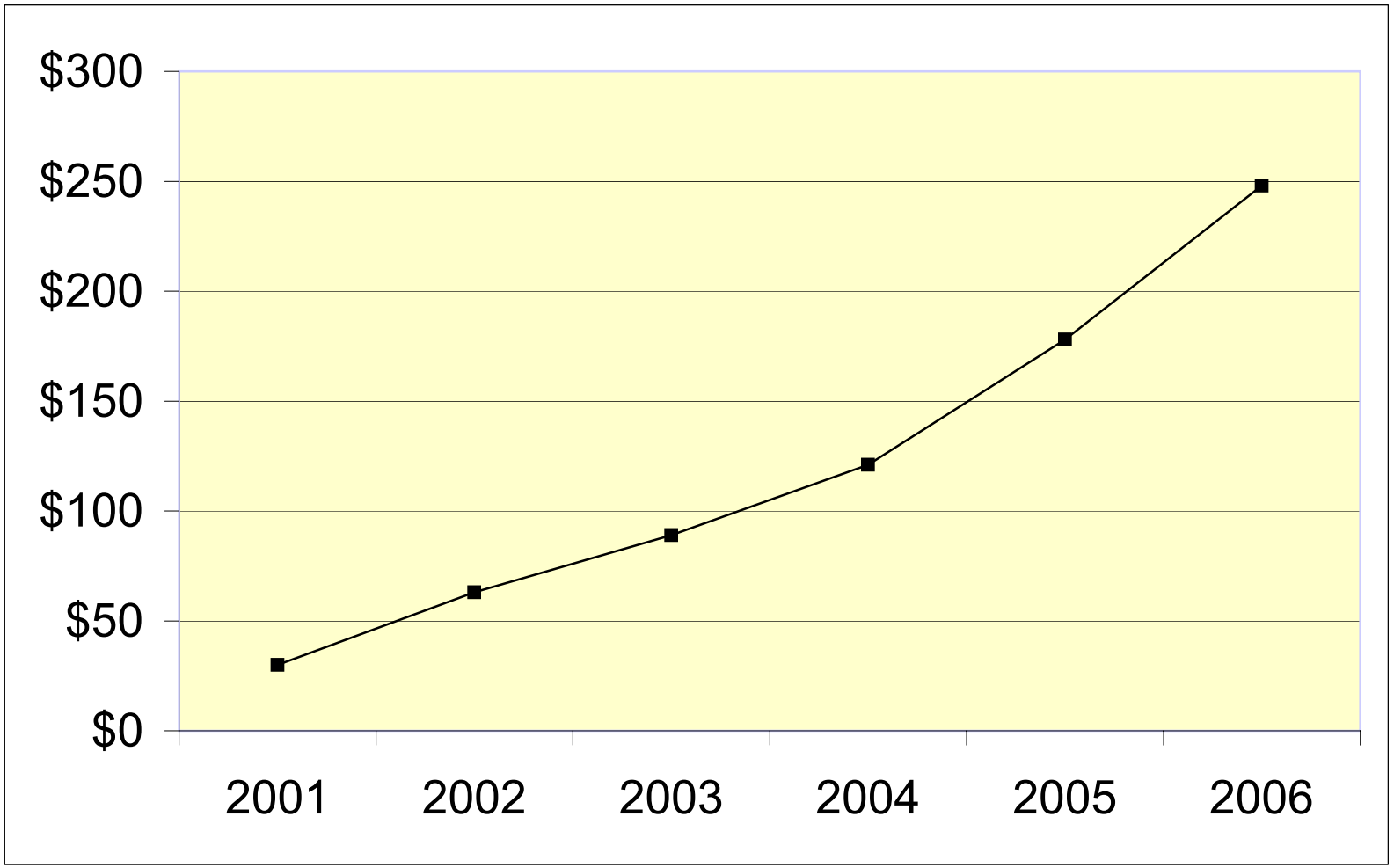
We have conducted a comprehensive education and outreach campaign to ensure that all suppliers, including small suppliers, have the information they need about the DMEPOS competitive bidding program. Preliminary education began months before the final regulation was issued, and the formal education campaign began on April 2, 2007, the day we announced the final regulation. For example, prior to opening the bidding window on May 15, 2007, we established a dedicated web site with a comprehensive array of important information, including a tool kit, fact sheets, web casts, and questions and answers. We also held Open Door Forums and sent listserv announcements to disseminate key information. After opening the bidding window, we held six bidders' conferences, during which we explained various parts of the bidding process. One of the bidders' conferences focused on small supplier issues. All of the bidders' conferences were held via teleconference to ensure maximum opportunities for suppliers to participate. We provided extensive education and support on the online bidding system. We also continued to issue answers to questions as they arose. Finally, we provided a toll-free help desk to help bidders with their issues. We believe this extensive educational campaign provided the information that potential bidders, including small suppliers, needed to submit their bids.

CMS is also aware that suppliers experienced difficulties with some aspects of CMS' implementation of the bidding process for Round I. In particular, there were intermittent technical problems with the online bidding system that presented challenges for suppliers. CMS presented these and other implementation issues to the PAOC during a meeting earlier this month in order to examine the experience from Round I with a view toward making improvements for Round II, including an enhanced online bidding system.

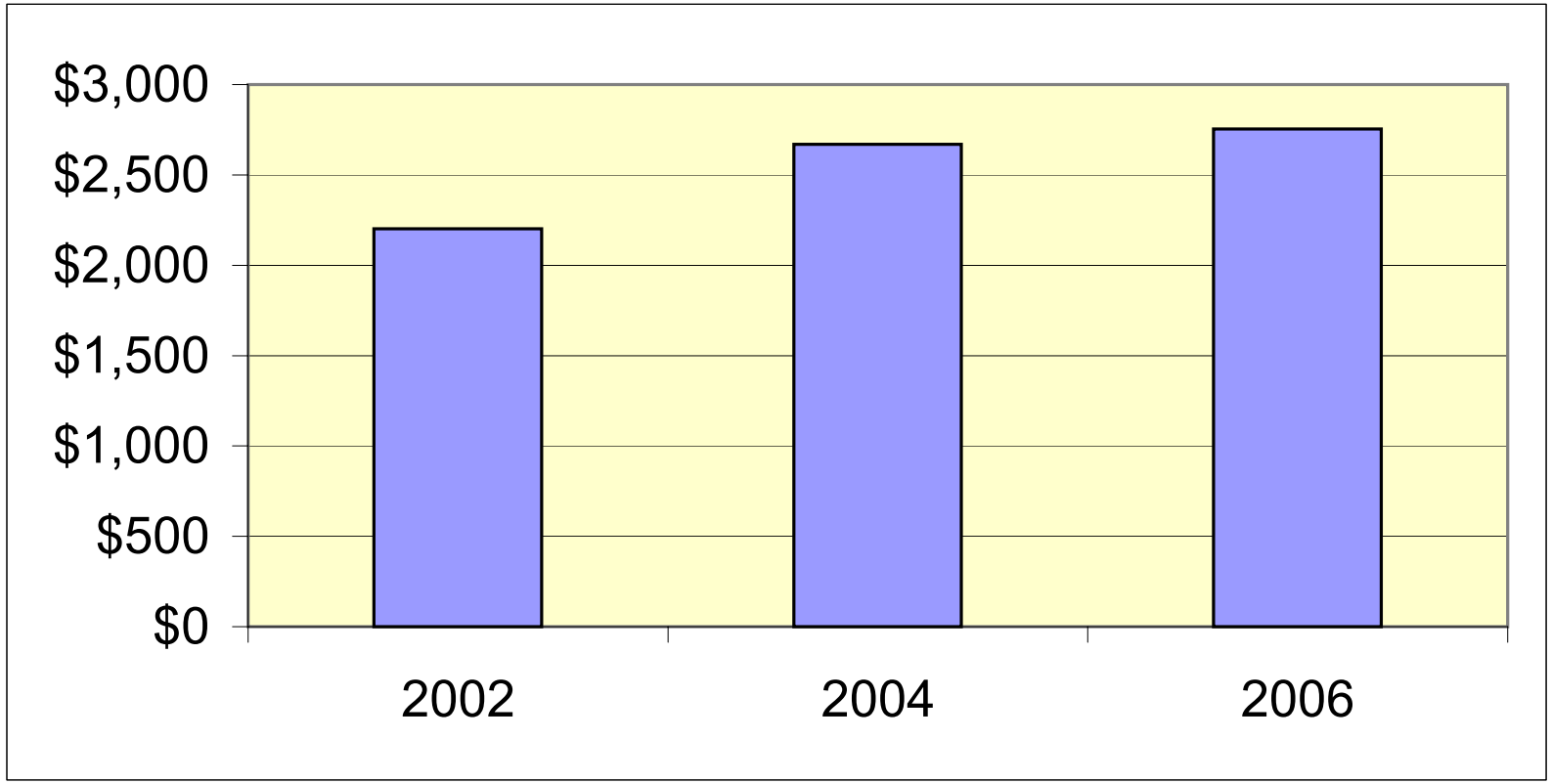
Conclusion

The new DMEPOS competitive bidding program is designed to bring Medicare payments to suppliers in better alignment with the competitive market. In addition, the program is an important part of the Administration's overall effort to eliminate fraudulent suppliers in Medicare and protect America's seniors. Overall, the competitive bidding program is expected to have a significant positive impact as reduced costs and improved access to higher-quality medical items and services is passed on to consumers and taxpayers with substantial savings to the Medicare program.

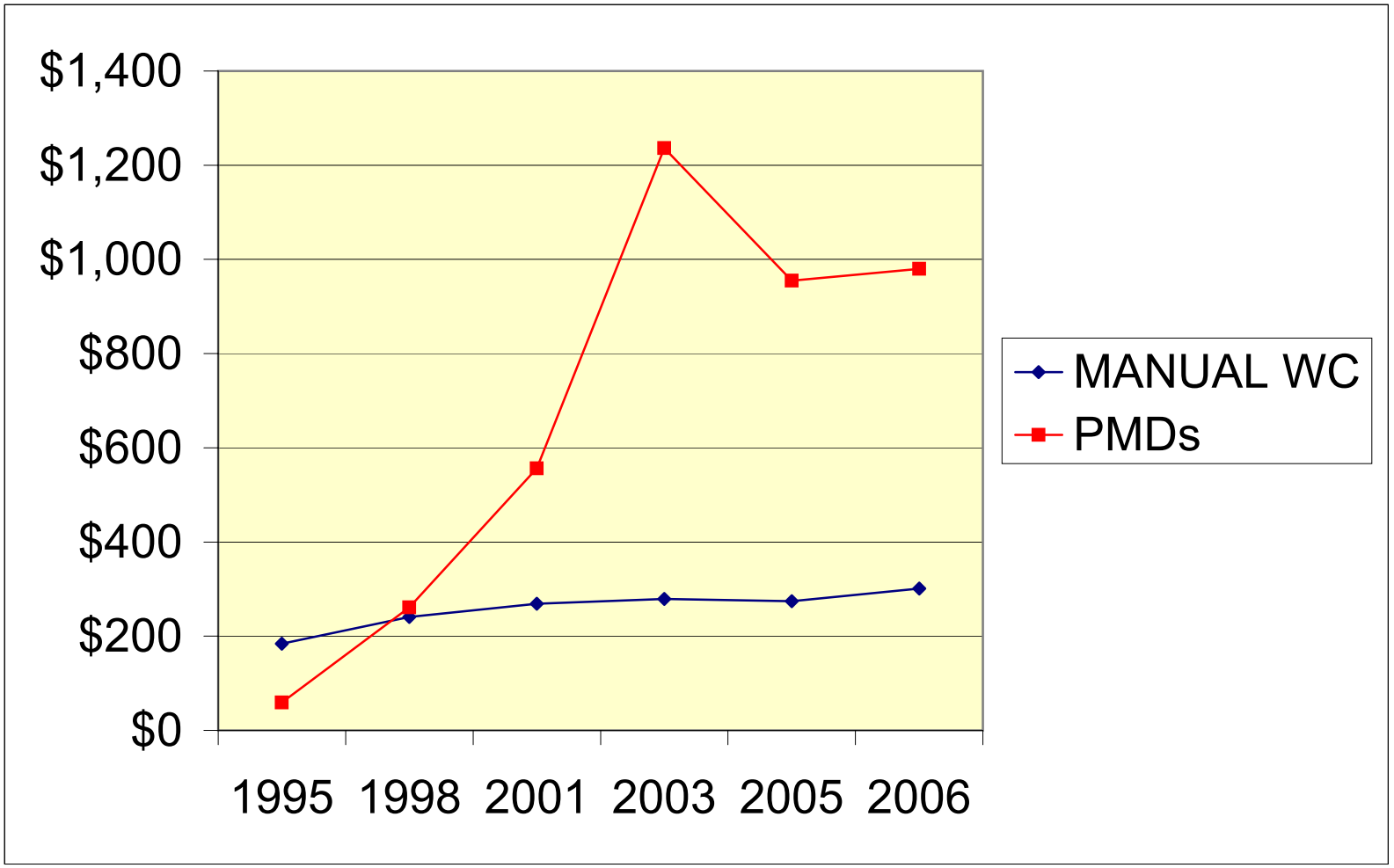
ATTACHMENT 2: NEGATIVE PRESSURE WOUND THERAPY (NPWT) EXPENDITURES FROM 2001 to 2006 (millions)



ATTACHMENT 3:
OXYGEN EXPENDITURES FROM 2002 to 2006 (millions)



ATTACHMENT 1: WHEELCHAIR EXPENDITURES FROM 1995 to 2006 (Millions)*



* Expenditures are for wheelchairs only and do not include expenditures for additional accessories